35 USC §112 Rejections

The Examiner rejected Claims 2-11 as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. The applicants have amended the claims to address the Examiner's rejections. Specifically, independent claim 9 has been reformulated in Jepson format and antecedent basis has been provided for "said first specific binding agent," thus correcting antecedent basis problems for claims 9 and 2. In claim 6, the language has been amended to clarify that the latex particles are a specific embodiment of the particulate direct label. Claims 6 and 7 were amended to clarify that they refer to two different populations of latex particles and that the two different populations of latex particles have the same color. Claim 3 was amended to make it dependent upon claim 9 instead of claim 1 since claim 1 was previously canceled and its language was incorporated into claim 9. No new matter was introduced by these amendments. A marked-up copy of the claims is attached. Applicants respectfully urge that all of the claims, as now presented, be allowed.

Applicant requests that the reference cited on the attached supplemental form 1449 be included in the record of the above-referenced patent application. This reference was included in a previous IDS submitted by a different law firm, but the Examiner crossed it off and noted "no copy provided" and "not of record in parent application." A copy of the reference, which is in English, is provided herewith.

The Commissioner is authorized to debit any fees deemed due or credit any overpayments to Deposit Account No. 15-0610. ✓

Respectfully submitted,
OPPEDAHL & LARSON, LLP

Karen Wade

Karen L. Wade, Ph.D.
Reg. No. 52,332
Marina T. Larson, Ph.D.
Reg. No. 32,038
P.O. Box 5068
Dillon, CO 80435-5068
970-468-6600

MARKED-UP CLAIMS

3. (twice amended) An assay device according to claim [1]9, wherein said first specific binding agent is a murine antibody.

6. (twice amended) An assay device according to claim 2, [comprising] wherein the particulate direct label comprises a first coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG.

7. (twice amended) An assay device according to claim 6, additionally comprising [same-coloured] a second coloured latex particles of the same colour as the first coloured latex particles and of diameter less than 0.5 micron sensitised solely with rabbit IgG, the ratio of said [co-sensitised] first particles to said second particles being at least 2:1.

9. (thrice amended) In an [An] assay device [of the type] wherein a sample liquid reconstitutes a labelled reagent and carries it into a detection zone and a control zone, binding of said labelled reagent in these zones revealing the assay result, the improvement wherein said labelled reagent comprises a particulate direct label co-sensitised with

(i) a first specific binding agent having specificity for an analyte, and

(ii) a non-specific protein which can participate in a control reaction with another specific binding agent which does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte is accomplished in said detection zone.

11. (twice amended) An assay device according to claim 9 [or claim 10], wherein said detection zone contains an immobilised specific bind agent which acts as a direct or indirect

capture means for hCG, said control zone contains an immobilised anti-rabbit IgG antibody, and said labelled reagent is coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG.